IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION FOR UNITED STATES LETTERS PATENT

a new and useful invention entitled:

SENSING CATHETER SYSTEM AND METHOD OF FABRICATION

jointly invented by:

Collin A. Rich

a U.S. citizen
residing at:
3530 Cloverlawn Ave., Ypsilanti, MI, 48197

and

F. Randall Grimes

a U.S. citizen
residing at:

1508 Westminster Place, Ann Arbor, MI 48104

prepared by:
J. Matthew Buchanan
BRINKS HOFER GILSON & LIONE
P.O. Box 10395
Chicago, IL 60610
(734) 302-6000

Attorney Docket No. 10989-007

SENSING CATHETER SYSTEM AND METHOD OF FABRICATION

REFERENCE TO PREVIOUS APPLICATIONS

[0001] This application claims the benefit of United States Provisional Applications No. 60/263,327 filed on January 22, 2001, and 60/278,634 filed on March 26, 2001.

FIELD OF THE INVENTION

[0002] The present invention relates generally to the field of medical catheters and similar devices used to make internal measurements. More particularly, the invention relates to catheters that include microminiature sensors for detecting and/or measuring various physiological parameters.

BACKGROUND OF THE INVENTION

[0003] Catheters with integrated physiologic sensors have a variety of applications. For example, sensing catheters enable the measurement of various physiological parameters, such as blood pressure, blood flow, temperature, thermal gradients, and various chemistries. Due to their minimally invasive design, these catheters can measure these parameters at remote sites within a patient.

[0004] While a small circumference allows a catheter to enter and navigate through tight spaces, such as the vasculature and other body lumens, it also makes it difficult to add additional functionality to the catheter. For example, integration of physiological sensors into a catheter can prove difficult because the sensor must be integrated within the narrow spaces of the catheter. Also, any required electrical bus must be incorporated into the catheter. For example, United States Patent No.

5,902,248 to Millar, et al. for a REDUCED SIZE CATHETER TIP MEASUREMENT DEVICE discloses a device that requires three leads for each sensor. Using this arrangement, the construction of a catheter with multiple sensors is difficult because numerous electrical leads must be packaged into the narrow geometries of the catheter. The use of an addressable electrical bus, such as that described in United States Patent No. 5,113,868 to Wise, et al. for a ULTRAMINIATURE PRESSURE SENSOR WITH ADDRESSABLE READ-OUT CIRCUIT, reduces the need for multiple leads for each sensor.

[0005] Due to their relatively small size, microminiaturize sensors, also referred to as microsensors, microfabricated sensors, MEMS (micro electrical mechanical systems), and BioMEMS, provide excellent candidates for integration into catheter designs. However, even these small sensors have proven difficult to mechanically integrate into the relatively soft material of most catheters, such as plastics. Furthermore, even though microminiature sensors are relatively small, it is difficult to place these sensors in a specific location within a catheter during the manufacturing process. Also, it is often useful to include some type signal conditioning circuit with the sensor. Signal conditioning circuits modify or condition an output of the sensor such that it is in a form acceptable for use by an appropriate receiving and/or analyzing device. Ideally, the conditioning circuit is placed near the sensor to minimize noise effects on the raw sensor output signal. Thus, the conditioning circuit must also be placed within the catheter, which adds complexity to the manufacturing process.

[0006] Considering these and other drawbacks and difficulties, there is a need for a sensor module with an integrated signal conditioning circuit that facilitates

catheter assembly. Also, there is a need for a sensing catheter system that includes an electrical bus that allows placement of multiple sensors in a catheter without necessitating multiple separate electrical leads for each sensor. Furthermore, there is a need for improved methods of fabricating sensing catheter systems.

SUMMARY OF THE INVENTION

[0007] The present invention provides a microminiature sensor module that includes a signal conditioning circuit and a physiological sensor. The module has electrical contacts that facilitate connection of the module to an electrical bus, such as within a sensing catheter.

[0008] The present invention also provides a sensing catheter system. In one embodiment, the system includes an electrical bus that provides electrical power and a signal return pathway to a microminiature sensor module. In one embodiment, the sensing catheter system comprises a catheter body having a circumferential wall and first and second lumens. The wall has at least one opening that exposes the second lumen. Two electrical leads are disposed in the second lumen, and can be used to provide electrical power and a return signal path. A microminiature sensor module is disposed in the opening and adjacent both of the electrical leads. Electrical contacts on the sensor module are in electrical communication with the two electrical leads. A sealant is disposed over the sensor module and fills the opening in the circumferential wall of the catheter body.

[0009] The present invention also provides methods of fabricating a sensing catheter system. A preferred method comprises forming a catheter body having a circumferential wall and first and second lumens, placing two electrical leads in the the

second lumen, forming an opening in the wall to expose the electrical leads, disposing a sensor module in the opening and adjacent the electrical leads, and placing the sensor module in electrical communication with the electrical leads. Lastly, the opening is sealed.

[0010] While the invention is defined by the claims appended hereto, additional understanding of the invention can be obtained by referencing the following description of preferred and alternate embodiments and the appended drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Figure 1 is a perspective view of a microminiature sensor module according to a preferred embodiment of the present invention.

[0012] Figure 2 is a side view of a microminiature sensor module according to an alternate embodiment of the present invention.

[0013] Figure 3 is a perspective view of a sensing catheter system incorporating microminiature sensing modules.

[0014] Figure 4 is a perspective view of a segment of a sensing catheter system according to a preferred embodiment of the present invention.

[0015] Figure 5 is a cross-sectional view taken along line I-I in Figure 4 illustrating a preferred arrangement of a microminiature sensor module and electrical leads within a catheter body.

[0016] Figure 6 illustrates a first alternative arrangement of a microminiature sensor module and electrical leads within a catheter body.

[0017] Figure 7 is a second alternative arrangement of a microminiature sensor module and electrical leads within a catheter body.

[0018] Figure 8 is a perspective view of a segment of a sensing catheter system according to an alternative embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED AND ALTERNATE EMBODIMENS OF THE INVENTION

[0019] The following description of preferred embodiments and methods provides examples of the present invention. The embodiments discussed herein are merely exemplary in nature, and are not intended to limit the scope of the invention in any manner. Rather, the description of these preferred embodiments and methods serves to enable a person of ordinary skill in the relevant art to make, use and perform the present invention.

[0020] Figure 1 illustrates a microminiature sensor module according to a preferred embodiment of the invention. As illustrated in the Figure, the module 10 preferably includes a substrate 12, a microminiature sensor 14, and a signal conditioning circuit 16. The sensor 14 and signal conditioning circuit 16 are disposed on the substrate 12. The substrate may be a separate element or an integral part of the sensor and/or circuit, or it may be optional if the sensor and circuit can be attached to each other without a substrate. The latter is thepreferred method if space is limited in a given application.

[0021] The microminiature sensor 14 can be any suitable microminiature sensor adapted to detect and/or measure various physiological parameters. For example, the sensor 14 can comprise a pressure sensor, a temperature sensor, a flow sensor, a velocity sensor, or a sensor adapted to measure specific chemistries, such as gas content (e.g., O_2 and CO_2) and glucose levels. Various specific examples of these types of microminiature sensors are known to those skilled in the

art, and any of these suitable sensors can be utilized in the sensor module of the present invention. While the specific type of sensor chosen will depend on the application of the catheter system, the sensor should be of a sufficiently small size in order to facilitate placement within a catheter according to the methods of the present invention.

[0022] The signal conditioning circuit 16 processes an output signal from the sensor 14 and prepares it for use by a receiving and/or analyzing device. For example, many systems receiving a pressure measurement as an input parameter prefer to receive the measurement output from a sensor in the form of a voltage, current, or frequency signal. Accordingly, the signal conditioning circuit 16 places the output signal of the sensor 14 into an appropriate form. Many different signal conditioning circuits are known to those skilled in the art, and any suitable circuit can be utilized. While the specific circuit chosen will depend upon the type of output signal needed in a particular sensing catheter system, the signal conditioning circuit should be of sufficiently small size to allow its placement in the sensor module of the present invention, and ultimately within the sensing catheter system according to the methods of the present invention.

[0023] Electrical connections 18 provide electrical communication between the sensor 14 and the signal conditioning circuit 16. The electrical connections 18 can be any suitable type of electrical connection, such as wirebonds between the sensor 14 and circuit 16. As illustrated in the Figure, the substrate 12 preferably includes circuit traces 20 and bond pads 22 that facilitate connection between the sensor 14 and circuit 16. Accordingly, in the preferred embodiment, the electrical connections 18 comprise a wirebond between the sensor 14 and a circuit trace 20 in

the substrate, and a wirebond between the signal conditioning circuit 16 and the appropriate circuit trace 20 on the substrate 12. Other possible embodiments include using ball-bonds between pads on the substrate and pads on the sensor and/or circuit. Ultrasonic, laser, or a similar welding process could likewise be used to form the electrical connections. Conductive adhesives, such as conductive silver epoxy, could also be used to form the connections.

[0024] The microminiature sensor module 10 also preferably includes at least two electrical contacts 24 that enable connection of the module 10 to an electrical bus (not illustrated in Figure 1). As illustrated in the Figure, the electrical contacts are preferably in electrical communication with the electrical connections 18 between the sensor 14 and the signal conditioning circuit 16. The use of two electrical contacts 24 allows the module 10 to be utilized with a dual lead electrical bus, such as the bus developed more fully below. However, it will be readily understood that any suitable number of electrical contacts can be employed. Also preferable, the electrical contacts 24 are arranged such that one electrical contact 24a lies at the beginning of an electrical path 26 that includes the sensor 14 and the signal conditioning circuit 16. The second electrical contact 24b preferably lies at the end of this path 26. Together, contacts 24a and 24b, and the associated leads and signal path, facilitate delivery of power to the sensor module from the receiving device, which also functions as a power supply. Furthermore, they provide a concurrent means of communication between the sensor module and the receiving device. In the preferred embodiment, modulation of the power supply current by the sensor module is the preferred method of transmitting the sensed data to the receiving device. Modulation of the supply voltage is the preferred method of

controlling the sensor module. Other methods such as frequency modulation, pulse width modulation, and/or other means known to those familiar with the art may also be used.

[0025] Figure 1 illustrates a preferred arrangement of the components of the sensor module 10. In this embodiment, the substrate 12 defines a main body region 28 that holds the sensor 14 and signal conditioning circuit 16. Also, the substrate 12 defines two opposing arms 30, each of which includes an electrical contact 24 at an end of the arm 30. The arms 30 are preferably centrally located on the body region 28. This arrangement facilitates connection of the module 10 to a dual lead electrical bus system, and allows for centralization of electrical connections 18 between the substrate 12, sensor 14, and signal conditioning circuit 16.

[0026] The substrate can be any substrate suitable for holding electrical componentry. Many examples of such substrates are known to those skilled in the art, and any can be used in the module. Furthermore, the substrate can be integrally formed with the sensor. The substrate can be either rigid or flexible. An example of a suitable rigid substrate includes a conventional printed circuit board, and an example of a suitable flexible substrate includes flexible circuit tape. Preferably, the substrate is flexible in order to facilitate movement (such as bending or twisting) of the module with a catheter body in which the module is incorporated.

[0027] Figure 1 illustrates a preferred embodiment in which both the sensor 14 and signal conditioning circuit 16 are both disposed on a top surface of the substrate 12. Various other types of arrangements can be utilized. For example, Figure 2 illustrates an alternative embodiment in which the substrate 12 is attached to a top surface of the sensor 14 and a side surface of the signal conditioning circuit

16. It will be readily understood that, while the Figure illustrates the substrate attached to the top surface of the sensor and a side surface of the circuit, the substrate can be attached to any one surface of the sensor and any different corresponding surface of the signal conditioning circuit, as long as the necessary electrical connections can be made between the sensor and circuit. Furthermore, the sensor and circuit may be oriented in different directions, such as placing the circuit on its side, so long as the face of the sensor is not prevented from taking measurements. For example, the substrate can be attached to a side surface of the sensor and a top surface of the signal conditioning circuit. This arrangement may provide additional flexibility to the module 10.

[0028] Figure 3 illustrates a sensing catheter system 100 according to the present invention. The catheter system includes a catheter 140 and a receiving and/or analyzing device 142. The catheter 140 includes a catheter body 144 and a luer assembly 146 for connection with a fluid manifold as typically used in a catheterrization operation. A data output assembly 148 provides communication between sensor modules 110 and the receiving/analyzing device 142.

[0029] The catheter 140 can be any type of conventional catheter, including catheters having a single sheath as well as those having multiple sheaths. Furthermore, the catheter may include other conventional componentry, such as guidewires, stents, and balloons.

[0030] The catheter body 144 houses the sensor modules 110 and the electrical bus that enables their operation. Figure 4 illustrates a segment of the catheter body that includes an arrangement of the components according to a preferred embodiment of the invention. In this embodiment, the catheter body 144

has a circumferential wall and defines first 162 and second 164 lumens. The circumferential wall 160 defines an opening 166 to the second lumen 164.

[0031] First 168 and second 170 electrical leads are disposed in the second lumen 164. Preferably, as illustrated in the Figure, the first 168 and second 170 leads are spaced apart from each other and extend parallel to each other. Also preferable, the electrical leads 168, 170 are ribbon forms of a suitable conductive material such as copper, with suitable insulation, such as varnish, to prevent shorting to each other. At some point along the length of the catheter, one or both of the leads may be woven into the peripheral braid of a braided catheter body. The catheter braid may serve as one of the leads. The catheter braid may also be used as a ground shield to reduce electrical noise in the leads.

[0032] The sensing catheter 100 also includes one or more microminiature sensor module 110 according to the present invention. The sensor module 110 is disposed in the opening 166 in the circumferential wall 160. Also, the module 110 lies adjacent the first 168 and second 170 electrical leads.

[0033] First 172 and second 174 electrical connections provide electrical communication between the first 168 and second 170 electrical leads and the first 124a and second 124b electrical contacts of the sensor module 110.

[0034] The use of dual electrical leads provides an electrical bus system to which sensor modules 110 can be easily connected. Furthermore, as illustrated in Figure 4, the electrical leads 168, 170 preferably extend beyond the length of the opening 166. This arrangement allows placement of the sensor module 110 at any point along the leads 168, 170 within the opening 166. Also, if the opening 166 is sufficiently large, multiple modules 110 can be placed along the leads 168, 170

within the opening. Alternatively, multiple openings 166 may be placed in the catheter at various locations to facilitate multiple sensor modules.

[0035] The sensor module 110 and leads 168, 170 can be arranged in any manner that establishes the necessary electrical communication between the leads 168, 170 and the module 110. Figure 5 illustrates a preferred arrangement of the module 110 and leads 168, 170 within the catheter body 144. In this embodiment, the sensor module 110 is disposed between the electrical leads 168, 170. Also, a retaining member 176, such as a u-shaped clip, is disposed over the sensor module 110 and engages the leads 168, 170 to form the electrical connections 172, 174 as electrical compression bonds.

[0036] Preferably, the catheter body 144 defines first 178 and second 180 shoulder regions. A sealant 182 is disposed over the components to fill the opening 166. Preferably, when shoulders 178, 180 are present, the sealant 182 extends into the shoulders 178, 180, facilitating retention of the module 110 in the opening 166.

[0037] Figure 6 illustrates an alternative arrangement of the components within the catheter body 144. In this embodiment, the second lumen 164 comprises a main channel portion 184 and first 186 and second 188 sub channels. Preferably, the sub channels 186, 188 lie below the main channel 184. The electrical leads 168, 170 are individually disposed in the first 186 and second 188 sub channels. Also, the sensor module 110 is disposed in the main channel 184. In this embodiment, electrical connections 172, 174 preferably comprise ball bonds disposed between the sensor module 110 and the electrical leads 168, 170.

[0038] Figure 7 illustrates a second alternative arrangement of the components within the catheter body 144. In this embodiment, the second lumen

164 comprises main 184 and sub 186, 188 channels, as in the first alternative arrangement illustrated in Figure 6. In this embodiment, however, the sub channels 186, 188 are disposed laterally from the main channel 184. Similar to the first alternative arrangement, the electrical leads 168, 170 are disposed within the sub channels 186, 188 and the sensor module 110 is disposed within the main channel 184. Electrical connections 172, 174 in this embodiment comprise wirebonds. To facilitate the connection of wirebonds to the components, the first 168 and second 170 electrical leads preferably each have at least one flat surface for attachment of the wirebond. Accordingly, suitable cross-sectional shapes for the electrical leads 168, 170 include square, rectangular, and half circle shapes.

[0039] Figure 8 illustrates an alternative embodiment of the sensing catheter. In this embodiment, like reference numbers refer to similar features and/or components illustrated above for the preferred embodiment.

[0040] In this embodiment, the electrical leads 268, 270 comprise conventional wires threaded through the second lumen 264. The wires terminate at a point at which the sensor module 210 is disposed in the opening 266. Solder joints form the electrical connections 272, 274 between the leads 268, 270 and the sensor module 210. Ultrasonic, laser, or a similar welding process could likewise be used to form the electrical connections. Conductive adhesives, such as conductive silver epoxy, could also be used. Furthermore, slots may be included in the substrate to aid the proper alignment of leads 268, 270.

[0041] The present invention also provides methods of fabricating a sensing catheter assembly. A preferred method according to the present invention comprises forming a catheter body having a circumferential wall and defining first

and second lumens. Next, two electrical leads are disposed within the second lumen to form an electrical bus for connection to a microminiature sensor module. The electrical leads can be disposed in the second lumen by either threading wires or ribbons through the lumen, or by forming the leads at that time of forming the catheter body. For example, the electrical leads can be co-extruded with the catheter body using an appropriate extruder.

[0042] The method also includes forming an opening in the circumferential wall of the catheter body such that the second lumen is exposed. When the electrical leads are contained within the second lumen, the opening also exposes the electrical leads. A microminiature sensor module according to the present invention is provided, and is disposed in the opening in the circumferential wall of the catheter body. The sensor module is disposed adjacent each of the electrical leads in order to facilitate connections. Next, the electrical contacts of the sensor module are placed in electrical communication with the electrical leads. Lastly, the opening is sealed with an appropriate material, such as an encapsulation or potting material.

[0043] When forming the electrical connections between the sensor module and the leads, any suitable connection method can be utilized. For example, a retaining member, such as a compressive clip, can be positioned adjacent the sensor module and the leads such that an electrical compression bond is formed between the components. Furthermore, ball bonds, wirebonds, or other suitable electrical bonds can be formed between the sensor module and each of the electrical leads.

[0044] The references cited in this disclosure, except to the extent they contradict any statement or definition made herein, are hereby incorporated by reference in their entirety.

[0045] The foregoing disclosure includes the best mode devised by the inventors for practicing the invention. It is apparent, however, that several variations in the apparatuses and methods of the present invention may be conceivable by one skilled in the art. Inasmuch as the foregoing disclosure is intended to enable one skilled in the pertinent art to practice the instant invention, it should not be construed to be limited thereby, but should be construed to include such aforementioned variations.